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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,816	08/09/2001	Peng George Wang	10114-009	4659

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BRINKS HOFER GILSON & LIONE  
P.O. Box 10395  
Chicago, IL 60610

EXAMINER

KHARE, DEVESH

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/925,816	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> Devesh Khare	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.  
4a) Of the above claim(s) 21-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4-22-2002</u> . | 6) <input type="checkbox"/> Other: ____  |

Applicant's election with traverse claims 1-20 of Group I, is acknowledged. The traversal is on the ground(s) that " this does not present an unusually large number of classes".

This is not found persuasive because the applicants' claims encompass the sugar modified linsidomine compounds (claims 1-20) and various methods that utilize sugar modified linsidomine compounds (claims 21-33), which would be burdensome to the examiner, as it cannot be assumed that the burden of search under two different classes are the same.

The requirement is still deemed proper and is therefore made FINAL.

The claims which read upon the elected invention are 1-20.

Claims 21-33 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-20 are before the examiner and an action on the merits of said claims is contained herein below.

**35 U.S.C. 112, second paragraph rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims **1-20** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(A) "Modified" is a relative term that renders the claims indefinite. In the absence of the specific modifications to the claimed compound core or distinct language to describe the structural modifications or the chemical names of modified or substituted compounds claimed, the identity of said modified compounds would be difficult to describe and the metes and bounds of said modified compounds applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

(B) The phrase "any carbohydrate" in claim 1, last line, is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant should consistently set forth the identity of the carbohydrate.

(C) The phrases "first sugar-modified SIN-1" and "second sugar-modified SIN-1" in claims 15 and 16, are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant should consistently set forth the identity of the sugar.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons of record.

**35 U.S.C. 103(a) rejection**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keefer et al. (Keefer) (U.S. Patent 6,290,981) in view of LaClair (U.S. Patent 6,140,041).

Claims 1-20 are drawn to a sugar-modified linsidomine (SIN-1) wherein the SIN-1 moiety is attached via a glycosidic bond or a bifunctional linker group to a sugar moiety. Additional claim limitations include the linker group is a carbonyl containing group or a glycosidic bond wherein the glycosidic bond is in a  $\alpha$  or  $\beta$  configuration; the sugar moiety is a monosaccharide glucose, galactose, or selected from the group consisting of glyceraldehydes, erythrose, threose, ribose, arabinose, xylose, lyxose, allose, altrose, glucose, mannose, gulose, idose, talose, erythrulose, ribulose, xylulose, psicose, fructose, sorbose, and tagatose; the sugar moiety is a furanose or pyranose ring structure, a disaccharide selected from the group consisting of sucrose, lactose and maltose; a pharmaceutical composition comprising the sugar modified SIN-1 and a pharmaceutically acceptable carrier comprising a liquid vehicle selected from the group consisting of water, Ringers-Lactate, DMSO, ethanol, and glycerol; and the pharmaceutical composition is in the form of a pill, tablet, capsule, syrup, emulsion, suspension, aerosol, suppository, ointment, gel or a paste.

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Keefer teaches the linsidomine chlorohydrate (SIN-1) which contains a NO donor nitric oxide functional group useful in treating erectile dysfunction in humans (col. 2, lines 60-65). Keefer discloses that the compound containing the nitric oxide functional group can be incorporated into or be part of a polymer by a covalent bond which enables localized release of NO and the localized release enhances the selectivity of action of the nitric oxide-releasing functional group (col. 5, lines 44-60). Keefer also discloses that peptides and oligonucleotides can be covalently attached to the nitric oxide functional groups to provide a concentrated release of NO (col. 5, lines 60-65). Furthermore, Keefer discloses the formulations dissolved in water or saline and in the form of tablet, capsule, gelatin and emulsion (col. 10, lines 56-65 through col. 11, lines 1-8). Keefer differs from the applicant's invention that Keefer does not provide an explicit example of sugar-modified linsidomine wherein the linsidomine is covalently attached to a sugar moiety via a carbonyl-containing group.

LaClair teaches fluorescent dyes conjugated to carbohydrates via a linker (abstract). LaClair discloses a dye labeled biomolecule covalently attached to a carbohydrate moiety via a carbonyl containing group (col. 9, lines 45-60). LaClair discloses the sugar-modified dye labeled biomolecules wherein the sugar moiety is glucose or maltose (figure 4).


It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the linsidomine moiety of Keefer as modified by which LaClair discloses the use of a carbonyl group containing linker to covalently attach a

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sugar moiety to a biomolecule, because Keefer discloses peptides and oligonucleotides can be covalently attached to the nitric oxide functional groups to provide a concentrated release of NO (col. 5, lines 60-65) in the treatment of erectile dysfunction in humans (col. 1, lines 11-18).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D., JD(3Y).  
Art Unit 1623  
April 2, 2004



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**